



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,900	03/19/2004	J. Kenneth Burkus	MSDI-134/PC361.18	8205
52196	7590	07/17/2007		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			07/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,900

Applicant(s)

BURKUS ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-36, 39-41, 43-48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732) in view of Paul et al. (US Pat. 6,258,125 B1).

Michelson discloses a surgical instrument assembly for distracting a spinal disc space, comprising: a first distractor (Fig. 7F, ref. 100, left) including: a first shaft (Fig. 7F, shaft near ref. numeral 100) extending between a proximal end (Fig. 7F, end near ref. 110) and a distal end (Fig. 7F, end near ref. 102); a first distractor tip (Fig. 7F, ref. 102, left) extending from the distal end of said first shaft (Fig. 7F), said first distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a first distraction height; a second distractor (Fig. 7F, ref. 100, right) including: a second shaft (Fig. 7F, shaft near ref. numeral 100, right) extending between a proximal end (Fig. 7F, end near ref. 110) and a distal end (Fig. 7F, end near ref. 102); a second distractor tip (Fig. 7F, ref. 102, right) extending from the distal end of said second shaft (Fig. 7F), said second distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a second distraction height substantially equal to said first distraction height, a guide

Art Unit: 3733

sleeve (Fig. 7F, ref. 340) defining a working channel (Fig. 7F, ref. 348) extending between a proximal end (Fig. 7F, end towards ref. 352) and a distal end (Fig. 7F, end towards ref. 344), wherein said first and second distractors are received in said working channel of said guide sleeve (Fig. 7F); and a distractor driver cap (Fig. 7F, ref. 420) coupled to the proximal end of said first and second distractors and said guide sleeve (Fig. 7F), said distractor driver cap having a side opening (Fig. 7F, the opening immediately distal from near where ref. 352 points) wherein said distractor driver cap is side-loaded onto said first and second distractors and said guide sleeve. A distal end of said guide sleeve includes a pair of opposite flanges (Fig. 7F, ref. 342) extending distally therefrom. The working channel includes a first working channel portion (Fig. 7F, portion of ref. 348 surrounding first distractor) for receiving said first distractor and a second working channel portion (Fig. 7F, portion of ref. 348 surrounding second distractor) for receiving said second distractor. The first working channel portion and said second working channel portion form a figure eight shape (Fig. 7F, since there are two circles formed by the working channel portions that lie next to each other, forming a figure eight shape). The guide sleeve includes a sleeve cap (Fig. 7F, proximal end portion of guide sleeve) at said proximal end of said guide sleeve, said sleeve cap including a proximal end ring (Fig. 7F, ring formed around distractors, near ref. 352) engageable to said distractor driver cap (Fig. 7F). The first distractor includes a first flange (Fig. 7F, ref. 110, left) on its proximal end defining a lip (Fig. 7F, rim of ref. 110, left) therearound and said second distractor includes a second flange (Fig. 7F, ref. 110, right) on its proximal end defining a lip (Fig. 7F, rim of ref. 110, right) therearound, said

driver cap including a distractor slot slidably receiving said first and second flanges therein. The distractor driver cap includes a guide sleeve slot slidably receiving said proximal end ring (Fig. 7E, slot immediately surrounding bores). The first distractor includes a first flange (Fig. 7F, ref. 110, left) on its proximal end defining a lip (Fig. 7F, rim of ref. 110, left) therearound and said second distractor includes a second flange (Fig. 7F, ref. 110, right) on its proximal end defining a lip (Fig. 7F, rim of ref. 110, right) therearound, said driver cap including a distractor slot (Fig. 7F, refs. 354) slidably receiving said first and second flanges therein. The first flange includes a proximal face (Fig. 7F, face just below ref. 110, left) having a hole (Fig. 7F, u-shaped hole just below ref. 110, left) therein and said second flange includes a proximal face (Fig. 7F, face just below ref. 110, right) having a hole (Fig. 7F, u-shaped hole just below ref. 110, right) therein, said distractor driver cap including a spring-biased plunger (column 20, lines 55-61) positionable in a corresponding one of said holes when said distractor driver cap is properly positioned thereon. The first distractor includes a projection (Fig. 3D, ref. 128) extending from a medial side of said first shaft; said second distractor includes a notch (Fig. 3F, notch in ref. 128) formed in a medial side of said second shaft, wherein when said first and second distractors are positioned in said guide sleeve said projection is received in said notch to prevent relative movement between said first and second distractors. The projection is cylindrically shaped, since it is a flattened cylinder (Fig. 3D, ref. 128).

Michelson discloses a surgical instrument assembly for distracting a spinal disc space, comprising: a first distractor (Fig. 7F, ref. 100, left) including: a first shaft (Fig.

Art Unit: 3733

7F, shaft near ref. numeral 100, left) extending between a proximal end (Fig. 7F, end near ref. 110left) and a distal end (Fig. 7F, end near ref. 102); a first distractor tip (Fig. 7F, ref. 102, left) extending from the distal end of said first shaft (Fig. 7F), said first distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a first distraction height; a second distractor (Fig. 7F, ref. 100, right) positionable along said first distractor including: a second shaft (Fig. 7F, shaft near ref. numeral 100, right) extending between a proximal end (Fig. 7F, end near ref. 110, right) and a distal end (Fig. 7F, end near ref. 102, right); a second distractor tip (Fig. 7F, ref. 102, right) extending from the distal end of said second shaft (Fig. 7F), said second distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a second distraction height; and a guide sleeve (Fig. 7F, ref. 340) defining a working channel (Fig. 7F, ref. 348) extending between a proximal end (Fig. 7F, end towards ref. 352) and a distal end (Fig. 7F, end towards ref. 344), wherein said first and second distractors are positionable in said working channel of said guide sleeve. The assembly further comprises a distractor driver cap (Fig. 7F, ref. 420) configured for side-loading on said at least one of said first and second distractors and said guide sleeve. The distal end surface (Fig. 3D, surface at tip of the component) of said at least one of said first and second distractors is linear (since one could draw a straight line across from lower left to upper right) and orthogonal to a central longitudinal axis of said at least one distractor (Fig. 3D, since the linear surface would be at a right angle to a longitudinal axis of the distractor). The first and second surfaces of said at least one distractor tip each include

a plurality of teeth formed therein (Fig. 3D, ref. 124). At least one of said first and second distractors said first surface includes a proximal portion (Fig. 3D, portion of surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128) and said second surface includes a proximal portion (Fig. 3D, portion of surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128), said proximal portions being generally parallel with one another (Fig. 3D) and said distal portions tapering toward one another from said proximal portions toward said distal end surface (Fig. 3D).

Michelson discloses a surgical instrument assembly for distracting a spinal disc space, comprising: a first distractor (Fig. 7F, ref. 100, left) including: a first shaft (Fig. 7F, shaft near ref. numeral 100) extending between a proximal end (Fig. 7F, end near ref. 110) and a distal end (Fig. 7F, end near ref. 102); a first distractor tip (Fig. 7F, ref. 102, left) extending from the distal end of said first shaft (Fig. 7F), said first distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a first distraction height; a second distractor (Fig. 7F, ref. 100, right) positionable along said first distractor including: a second shaft (Fig. 7F, ref. 102, right) extending between a proximal end (Fig. 7F, end near ref. 110, right) and a distal end (Fig. 7F, end near ref. 102); a second distractor tip (Fig. 7F, ref. 102, right) extending from the distal end of said second shaft (Fig. 7F), said second distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a second distraction height, and a guide sleeve (Fig. 7F, ref. 340) defining a working channel (Fig. 7F, ref. 348) extending between a proximal end

(Fig. 7F, end towards ref. 352) and a distal end (Fig. 7F, end towards ref. 344), wherein said first and second distractors are positionable in said working channel of said guide sleeve. The assembly further comprises a distractor driver cap (Fig. 7F, ref. 420) configured for side-loading on said at least one of said first and second distractors and said guide sleeve. The distal end surface (Fig. 3D, surface at tip of the component) of said at least one of said first and second distractors is linear (since one could draw a straight line across from lower left to upper right) and orthogonal to a central longitudinal axis of said at least one distractor (Fig. 3D, since the linear surface would be at a right angle to a longitudinal axis of the distractor). The first and second surfaces of said at least one distractor tip each include a plurality of teeth formed therein (Fig. 3D, ref. 124). At least one of said first and second dissectors said first surface includes a proximal portion (Fig. 3D, portion of surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128) and said second surface includes a proximal portion (Fig. 3D, portion of surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128), said proximal portions being generally parallel with one another (Fig. 3D) and said distal portions tapering toward one another from said proximal portions toward said distal end surface (Fig. 3D).

Michelson discloses a surgical instrument assembly for distracting a spinal disc space, comprising: a first distractor (Fig. 7F, ref. 100, left) including: a first shaft (Fig. 7F, shaft near ref. numeral 100) extending between a proximal end (Fig. 7F, end near ref. 110) and a distal end (Fig. 7F, end near ref. 102); a first distractor tip (Fig. 7F, ref.

102, left) extending from the distal end of said first shaft, said first distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a first distraction height; a second distractor (Fig. 7F, ref. 100, right) positionable along said first distractor including: a second shaft (Fig. 7F, shaft near ref. numeral 100, right) extending between a proximal end (Fig. 7F, end near ref. 110, right) and a distal end (Fig. 7F, end near ref. 102, right); a second distractor tip (Fig. 7F, ref. 102, right) extending from the distal end of said second shaft, said second distractor tip including opposite first and second surfaces (Fig. 3D, surfaces with teeth opposite each other in Fig. 3D) defining a second distraction height substantially equal to said first distraction height; and a guide sleeve (Fig. 7F, ref. 340) defining a working channel (Fig. 7F, ref. 348) extending between a proximal end (Fig. 7F, end towards ref. 352) and a distal end (Fig. 7F, end towards ref. 344), wherein said first and second distractors are positionable in said working channel of said guide sleeve. The assembly further comprises a distractor driver cap (Fig. 7F, ref. 420) configured for side-loading on said at least one of said first and second distractors and said guide sleeve. The distal end surface (Fig. 3D, surface at tip of the component) of said at least one of said first and second distractors is linear (since one could draw a straight line across from lower left to upper right) and orthogonal to a central longitudinal axis of said at least one distractor (Fig. 3D, since the linear surface would be at a right angle to a longitudinal axis of the distractor). The first and second surfaces of said at least one distractor tip each include a plurality of teeth (Fig. 3D, ref. 124) formed therein. The at least one of said first and second distractors said first surface includes a proximal portion (Fig. 3D, portion of

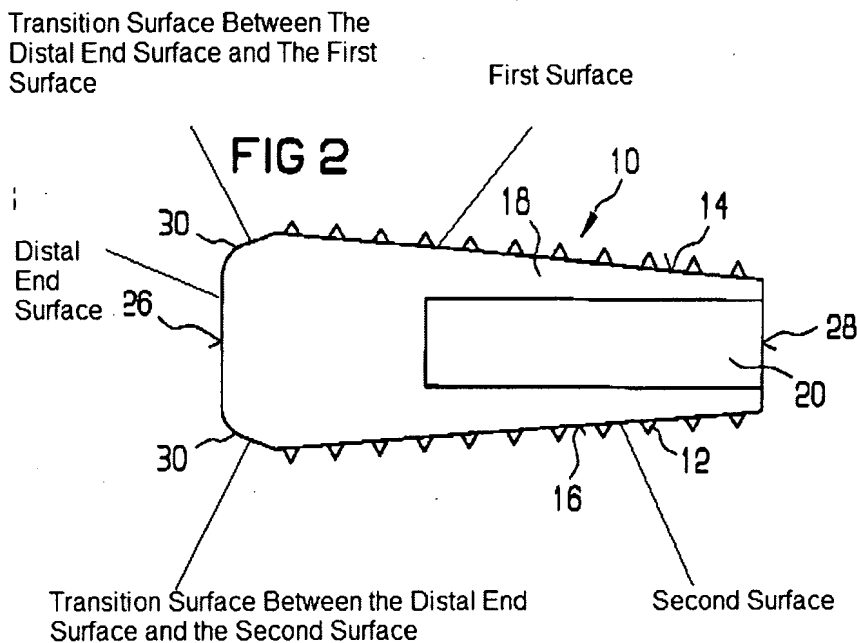
surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128) and said second surface includes a proximal portion (Fig. 3D, portion of surface closer to ref. 128) and a distal portion (Fig. 3D, portion closest to tip of component, farthest away from ref. 128), said proximal portions being generally parallel with one another (Fig. 3D) and said distal portions tapering toward one another from said proximal portions toward said distal end surface (Fig. 3D). The first and second distraction heights are equal (Fig. 7F, ref. 102) (Fig. 3D).

Michelson does not disclose at least one of said first and second distractor tips includes a transition surface extending between a distal end surface and said first surface of said at least one distractor tip and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said transition surfaces each having a curvature shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane.

Paul et al. disclose a distractor tip (since it distracts, column 4, lines 18-20) (Fig. 2, below) including a transition surface extending between a distal end and said first surface of said at least one distractor and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said transition surfaces each having a curvature (column 4, lines 16-20) shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane, in order to facilitate insertion of the device (column 4, lines 16-20).

Art Unit: 3733

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distractor tips of Michelson with each having a transition surface extending between a distal end surface and said first surface of said at least one distractor and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said surfaces each having a curvature shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane as taught by Paul et al., in order to facilitate insertion of the device (column 4, lines 16-20).



With regard to claim 24, Michelson in view of Paul et al. disclose the claimed invention except for the first distractor tip being integrally formed with said first shaft and said second distractor tip being integrally formed with said second shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made

Art Unit: 3733

to have constructed the distractor tips as being integrally formed with their respective shafts, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

With regard to claims 21-25, Michelson does not disclose the second distractor including a recessed area extending along a medial side thereof. The recessed area is a concave surface. The recessed area is configured to permit rotation of a surgical instrument positioned adjacent thereto. The first distractor includes a convex surface along a medial side thereof, and said second distractor includes a convex surface along a medial side thereof.

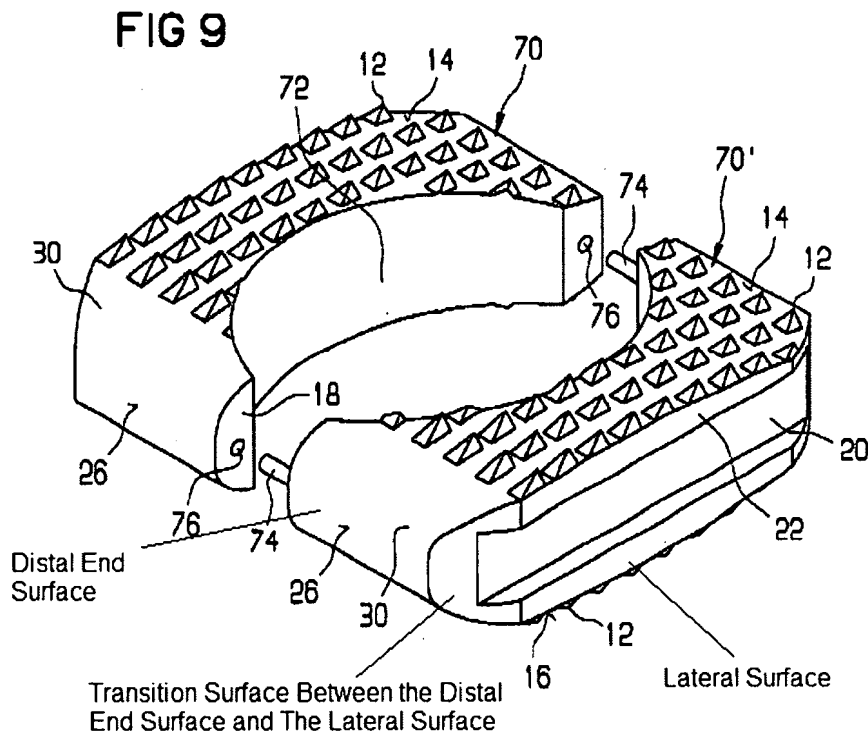
Paul et al. disclose a distractor (since it distracts, column 4, lines 18-20) (Fig. 2, ref. 10) with a recessed area (Fig. 2, ref. 20) extending along a medial side (Fig. 2, ref. 18) thereof. The distractor includes a convex surface (Fig. 2, ref. 18) along a medial side thereof. These surfaces facilitate the insertion of a surgical instrument (column 3, lines 49-50).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distractors of Michelson with the convex surfaces and the recessed areas along a medial side as taught by Paul et al., in order to facilitate the insertion of a surgical instrument (column 3, lines 49-50).

With regard to claims 36 and 56, Michelson discloses the claimed invention except for each of said first and second distractor tips including: a distal end surface; a lateral surface; a transition surface extending between said distal end surface and said lateral surface, said transition surface having a second curvature (since it is curved, Fig. 9) generally corresponding to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in an axial plane.

Paul et al. disclose a distractor (Fig. 9, ref. 70) including a transition surface (Fig. 9, below) between the distal end and the lateral surface, which facilitates insertion of the device (column 4, lines 16-20).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distractor of Michelson with the transition surface between the distal end and the lateral surface, in order to facilitate insertion of the device (column 4, lines 16-20).



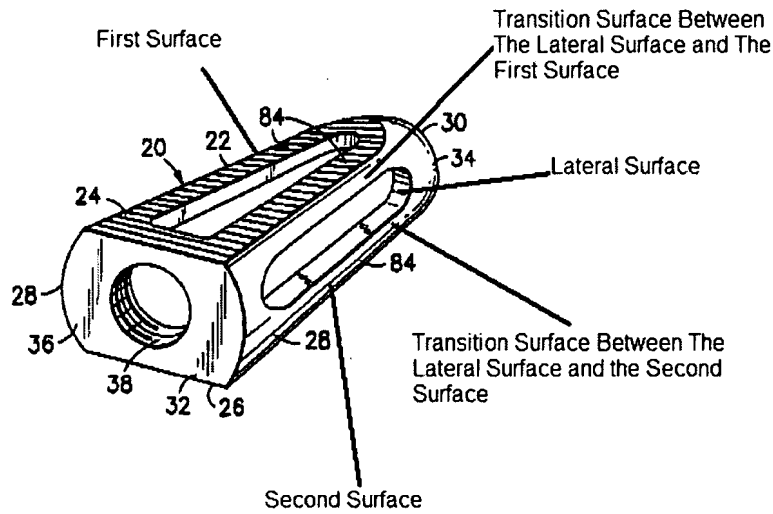
Claims 37, 38, 42 and 49 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732) in view of Paul et al. (US Pat. 6,258,125 B1) in view of Henry et al. (US Pat. 5,766,252).

Michelson in view of Paul et al. disclose the claimed invention except for each of said first and second distractor tips further includes a transition surface extending between said lateral surface and said first surface and a transition surface extending between said lateral surface and said second surface, said transition surfaces each having a third curvature shaped to generally correspond in shape to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a coronal plane.

Henry et al. disclose a transition surface extending between a lateral surface and said first surface (see Fig. 1, below), and a transition surface extending between said lateral surface and said second surface, said transition surfaces each having a third curvature (column 3, lines 42-49) shaped to generally correspond in shape to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a coronal plane, the transition surface facilitating appropriate introduction and placement of the device during implant, while reducing the risk of injury to surrounding tissue (column 1, lines 39-42).

It would have been obvious to have constructed the distractor tips of Michelson with the transition surface of Henry et al., in order to facilitate appropriate introduction and placement of the device, while reducing the risk of injury to surrounding tissue (column 1, lines 39-42).

Figure 1



Claims 53, 54, 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732) in view of Henry et al. (US Pat. 5,766,252).

Michelson discloses the claimed invention except for each of said first and second distractor tips further including a transition surface extending between said lateral surface and said first surface and a transition surface extending between said lateral surface and said second surface, said transition surfaces each having a third curvature shaped to generally correspond in shape to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a coronal plane.

Henry et al. discloses a transition surface (Fig. 1, above) extending between a lateral surface and said first surface, and a transition surface extending between said lateral surface and said second surface, said transition surfaces each having a third

curvature (column 3, lines 42-49) shaped to generally correspond in shape to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a coronal plane, the transition surfaces facilitating appropriate introduction and placement of the device during implant, while reducing the risk of injury to surrounding tissue (column 1, lines 39-42).

It would have been obvious to have constructed the distractor tips of Michelson with the transition surfaces of Henry et al., in order to facilitate appropriate introduction and placement of the device, while reducing the risk of injury to surrounding tissue (column 1, lines 39-42).

Claims 55, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 5,505,732) in view of Henry et al. (US Pat. 5,766,252) further in view of Paul et al. (US Pat. 6,258,125 B1).

Michelson and Henry et al. disclose the claimed invention except for at least one of said first and second distractor tips including a transition surface extending between a distal end surface and said first surface of said at least one distractor tip and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said transition surfaces each having a curvature shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane.

Paul et al. disclose a distractor tip (since it distracts, column 4, lines 18-20) (Fig. 2, above) including a transition surface extending between a distal end surface and said

Art Unit: 3733

first surface of said at least one distractor and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said transition surfaces each having a curvature (column 4, lines 16-20) shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane, in order to facilitate insertion of the device (column 4, lines 16-20).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distractor tips of Michelson with each having a transition surface extending between a distal end surface and said surface of said at least one distractor and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said transition surfaces each having a curvature shaped to generally correspond to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane, in order to facilitate insertion of the device (column 4, lines 16-20).

Response to Arguments

Applicant's arguments filed 04/17/2007 have been fully considered but they are not persuasive.

With regard to claim 38, the Examiner inadvertently omitted this claim number from the above rejections due to a typographical error. It has been rejected for essentially the same reasons as claim 20, as the claim language is similar, and Applicant is correct in assuming this. Claim 37 is dependent on claim 38 and as such is

Art Unit: 3733

grouped under the 35 U.S.C 103 rejection as being unpatentable over Michelson (US Pat. 5,505,732) in view of Paul et al. (US Pat. 6,258,125 B1) in view of Henry et al. (US Pat. 5,766,252).

With regard to Applicant's argument that the prior art does not disclose first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane, the Examiner respectfully disagrees. The definition of "correspond" according to The American Heritage Dictionary of the English Language is "to be similar or equivalent in character, quantity, origin, structure, or function." The curvature of the prior art references naturally all contain at least one curve and are all therefore similar in structure to anything else that has a curvature. The inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane has a curvature, therefore the curvature of the prior art references is similar in structure to the curvature of the inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane, and the curvatures correspond. Furthermore, the geometric points found along the curvature of the devices and geometric points along the curvature of the inner portion of a cortical rim could be related (e.g. graphically/mathematically) and the curvatures would therefore correspond in that manner also. With regard to Applicant's argument that Paul teaches away from this concept of using corresponding curvatures, the Examiner respectfully disagrees. As Applicant states on page 13, third paragraph, the edges disclosed by Paul are rounded

and therefore have a curvature, and the above reasoning applies. Thus Paul discloses a curvature that corresponds to the curvature of the inner portion of a cortical rim.

With regard to Applicant's argument that one of ordinary skill in the art would not be motivated to include the rounded edges of Paul on the device of Michelson, the Examiner respectfully disagrees. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distractor tips of Michelson with each having a transition surface extending between a distal end surface and said first surface of said at least one distractor and a transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said surfaces each having a curvature shaped to generally correspond to a curvature of an inner portion of a cortical rim of vertebral endplates in a sagittal plane as taught by Paul et al., in order to facilitate insertion of the device (column 4, lines 16-20). The rounded edges would make it easier to insert the distractor into the body.

With regard to Applicant's argument that one of ordinary skill in the art would not have been motivated to look to permanently implanted devices to modify temporarily implanted devices the Examiner respectfully disagrees. Since both of the devices are being implanted in the body at one point, one of ordinary skill would look to either permanent or temporary devices to find advantageous approaches to facilitate the initial implantation of the device. The motivations supplied in the previous rejections are consistent with this rationale, as the motivations all revolve around the initial implantation of the respective devices (i.e. Paul et al. "in order to facilitate insertion of

the device"; i.e. Henry et al. "the transition surface facilitating appropriate introduction and placement of the device during implant, while reducing the risk of injury to surrounding tissue").

With regard to Applicant's argument that Paul does not disclose that the recessed area is configured to permit rotation of a surgical instrument positioned adjacent thereto, the Examiner respectfully disagrees. With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Paul, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The recessed area of Paul is capable of allowing rotation of a surgical instrument which is positioned adjacent to it (e.g. a drill that is positioned near it).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER